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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,171	04/16/2002	Andrew Lever	117-372	8487
23117	7590	10/06/2004	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			HILL, MYRON G	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,171

Applicant(s)

LEVER ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1- 10, 12- 18, and 20- 23 is/are pending in the application.
- 4a) Of the above claim(s) 1- 6, and 12- 18, and 20- 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7- 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/10/01.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II (claims 7- 10) in the reply filed on 24 May 2004 is acknowledged. The traversal is on the ground(s) that there was a lack of showing that it is an additional burden to search the other groups and that compact prosecution and the public interest is served by doing so. This is not found persuasive because the requirement for restriction in a 371 application is Lack of Unity, not burden. Applicant has not stated on what grounds the Lack of Unity was not proper. Additionally, applicant requests rejoinder of allowed products under *In re Ochiai*. It is noted that the possibility of rejoinder was made of record in the restriction requirement and will be considered at the time allowability is indicated.

Claims 1- 6, 12- 18, and 20- 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

This action is on claims 7- 10.

Objection to the Specification

The specification is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See at least page 27, line 22.

Sequence Requirements

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on as follows:

The specification does not contain sequence identifiers (SEQ ID#s) in all locations where sequences are disclosed, see at least page 24 and Figures 3a- 3e. The sequence shown in the figures is not identified by a SEQ ID# in the figure or in the Brief Description of the Figures section.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this Office Action will be held non-responsive.

Claim Objections

Claim 10 is objected to because of the following informalities: the claim should readtherapeutic..., or antigenic The underlined portions indicate suggestions to fix grammatical agreement. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1648

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7- 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a SIV vector with a packaging signal and a heterologous gene that can be expressed.

The specification does not describe what is required for packaging, only what leads to defective packaging. It only describes what is necessary not what is sufficient. The experiments show what is required to ablate packaging but does not show what is the minimum sequence required for packaging SIV.

The specification does not describe fragments, fragments of 10 nucleotides or more, or variants that that can be used to package SIV. The only sequence disclosed that fully packages SIV is the WT sequence (Table 1). Applicant has not shown fragments of 10 or more nucleotides that can act as packaging signals or variants thereof. Applicant has not shown that SEQ ID# 1 is sufficient for packaging.

Thus, it is concluded that Applicant was not in possession of the invention as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7- 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Rizvi *et al.* (IDS).

The claims are drawn to a SIV vector with a packaging signal and a heterologous gene that can be expressed. Claim 8 is drawn to regions comprising as well as fragments and this reads on any wild type sequence or part thereof.

Rizvi *et al.* teach SIV vectors that can be packaged with different 5 prime region sequences. The expressed hygromycin would be antigenic if injected into a rabbit or human. The sequences used by Rizvi *et al.* are based on SIV mac239 as are the claimed sequence.

Thus, Rizvi *et al.* anticipate the claimed invention.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 7- 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Lauermann (US 6635472).

The claims are drawn to a SIV vector with a packaging signal and a heterologous gene that can be expressed. Claim 8 is drawn to regions comprising as well as fragments and this reads on any wild type sequence or part thereof.

Lauermann teaches a viral vector that contains an SIV packaging signal and a heterologous gene (claims 1, 3, 7, 9, 13- 16 and 19). The claims also encompass mutations that will result in variants.

Thus, Lauermann anticipate the claimed invention.

Conclusion


No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rud *et al.*, 1994 is cited as additional information on proviral clones. This reference was cited repeatedly in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Mylon G. Hill
Patent Examiner
September 30, 2004


JAMES HOUSEL 10/1/04
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